

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET		PAYMENT IDENTIFICATION NUMBER: Write the Payment Identification Number on your check.		
A completed Cover Sheet must accompany each original application or supplement subject to fees. The following actions must be taken to properly submit your application and fee payment:				
<ol style="list-style-type: none"> 1. Electronically submit the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent. 2. Include a printed copy of this completed Cover Sheet with a check made payable to the Food and Drug Administration. Remember that the Payment Identification Number must be written on the check. 3. Mail Check and Cover Sheet to the US Bank Lock Box, FDA Account, P.O. Box 956733, St. Louis, MO 63195-6733. <i>(Note: In no case should payment be submitted with the application.)</i> 4. If you prefer to send a check by a courier, the courier may deliver the check and Cover Sheet to: US Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314-418-4821 if you have any questions concerning courier delivery.) 5. For Wire Transfer Payment Procedures, please refer to the MDUFMA Fee Payment Instructions at the following URL: http://www.fda.gov/cdrh/mdufma/faqs.html#3a. You are responsible for paying all fees associated with wire transfers. 6. Include a copy of this completed Cover Sheet in volume one of the application when submitting to the FDA at either the CBER or CDRH Document Mail Center. 				
1. COMPANY NAME AND ADDRESS (Include name, street address, city, state, country, and post office code) 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)	2. CONTACT NAME 2.1 E-MAIL ADDRESS 2.2. TELEPHONE NUMBER (Include Area Code) 2.3 FACSIMILE (FAX) NUMBER (Include Area Code)			
3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following website: http://www.fda.gov/oc/mdufma)				
<table style="width: 100%; border: none;"> <tr> <td style="width: 50%; vertical-align: top;"> <u>Select an application type:</u> <input type="checkbox"/> Premarket notification (510(k)); except for third party reviews <input type="checkbox"/> Biologic License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) </td> <td style="width: 50%; vertical-align: top;"> <u>3.1 Select one of the types below:</u> <input type="checkbox"/> Original Application <u>Supplement Types:</u> <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP) </td> </tr> </table>			<u>Select an application type:</u> <input type="checkbox"/> Premarket notification (510(k)); except for third party reviews <input type="checkbox"/> Biologic License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR)	<u>3.1 Select one of the types below:</u> <input type="checkbox"/> Original Application <u>Supplement Types:</u> <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)
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4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status.) <table style="width: 100%; border: none;"> <tr> <td style="width: 50%; vertical-align: top;"> <input type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA 4.1 If Yes, please enter your Small Business Decision Number: _____ </td> <td style="width: 50%; vertical-align: top;"> <input type="checkbox"/> NO, I am not a small business </td> </tr> </table>			<input type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA 4.1 If Yes, please enter your Small Business Decision Number: _____	<input type="checkbox"/> NO, I am not a small business
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5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS ? IF SO, CHECK THE APPLICABLE EXCEPTION.				
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6. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITIONS OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).)				
<input type="checkbox"/> YES <input type="checkbox"/> NO				
7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (FOR FISCAL YEAR ____)				